Attorney's Docket No. KJ-100 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

NEW APPLICATION TRANSMITTAL

Transmitted herewith for filing is the patent application of

Inventor(s): Jacquelyn R. Doyle, and
Kenneth F. Short

WARNING: Patent must be applied for in the name(s) of all of the actual inventor(s). 37 CFR 1.41(a) and 1.53(b).

For (title):

Wound Irrigation and Debriding System

CERTIFICATION UNDER 37 CFR 1.10

I hereby certify that this New Application Transmittal and the documents referred to as enclosed therein are being deposited with the United States Postal Service on this date July 30, 1999 in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number EJ915436074US, addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

Arthur A. Smith, Jr.
(type or print name of person mailing paper)

Arthur A. Smith, Jr.
signature of person mailing paper

NOTE: Each paper or fee referred to as enclosed herein has the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 CFR 1.10(b).

WARNING: Certificate of mailing (first class) or facsimile transmission procedures of 37 CFR 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.

1. **Type of Application**

This new application is for a(n)

(check one applicable item below)

XX Original (nonprovisional)

☐ Design

☐ Plant

WARNING: *Do not use this transmittal for a completion in the U.S. of an International Application under 35 U.S.C. 371(c)(4), unless the International Application is being filed as a divisional, continuation or continuation-in-part application.*

WARNING: *Do not use this transmittal for the filing of a provisional application.*

NOTE: If one of the following 3 items apply, then complete and attach ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF A PRIOR U.S. APPLICATION CLAIMED and a NOTIFICATION IN PARENT APPLICATION OF THE FILING OF THIS CONTINUATION APPLICATION.

☐ Divisional.

☐ Continuation.

☐ Continuation-in-part (C-I-P).

2. **Benefit of Prior U.S. Application(s)** (35 U.S.C. 119(e), 120, or 121)

NOTE: If the new application being transmitted is a divisional, continuation or a continuation-in-part of a parent case, or where the parent case is an International Application which designated the U.S., or benefit of a prior provisional application is claimed, then check the following item and complete and attach ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

WARNING: *If an application claims the benefit of the filing date of an earlier filed application under 35 U.S.C. 120, 121 or 365(c), the 20-year term of that application will be based upon the filing date of the earliest U.S. application that the application makes reference to under 35 U.S.C. 120, 121 or 365(c). (35 U.S.C. 154(a)(2) does not take into account, for the determination of the patent term, any application on which priority is claimed under 35 U.S.C. 119, 365(a) or 365(b).) For a c-i-p application, applicant should review whether any claim in the patent that will issue is supported by an earlier application and, if not, the applicant should consider canceling the reference to the earlier filed application. The term of a patent is not based on a claim-by-claim approach. See Notice of April 14, 1995, 60 Fed. Reg. 20,195, at 20,205.*

WARNING: *When the last day of pendency of a provisional application falls on a Saturday, Sunday, or Federal holiday within the District of Columbia, any nonprovisional application claiming benefit of the provisional application must be filed prior to the Saturday, Sunday, or Federal holiday within the District of Columbia. See 37 C.F.R. § 1.78(a)(3).*

☐ The new application being transmitted claims the benefit of prior U.S. application(s) and enclosed are ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

3. **Papers Enclosed That Are Required for Filing Date under 37 CFR 1.53(b) (Regular) or 37 CFR 1.153 (Design) Application**

_____ Pages of specification

_____ Pages of claims

_____ Pages of Abstract

_____ Sheets of drawing

☐ formal

XX informal

WARNING: *DO NOT submit original drawings. A high quality copy of the drawings should be supplied when filing a patent application. The drawings that are submitted to the Office must be on strong, white, smooth, and non-shiny paper and meet the standards according to § 1.84. If corrections to the drawings are necessary, they should be made to the original drawing and a high-quality copy of the corrected original drawing then submitted to the Office. Only one copy is required or desired. Comments on proposed new 37 CFR 1.84. Notice of March 9, 1988 (1990 O.G. 57-62).*

NOTE: "Identifying indicia, if provided, should include the application number or the title of the invention, inventor's name, docket number (if any), and the name and telephone number of a person to call if the Office is unable to match the drawings to the proper application. This information should be placed on the back of each sheet of drawing a minimum distance of 1.5 cm. (5/8 inch) down from the top of the page." 37 C.F.R. 1.84(c)).

(complete the following, if applicable)

☐ The enclosed drawing(s) are photograph(s), and there is also attached a "PETITION TO ACCEPT PHOTOGRAPH(S) AS DRAWING(S)." 37 C.F.R. 1.84(b).

4. Additional papers enclosed

☐ Preliminary Amendment

☐ Information Disclosure Statement (37 CFR 1.98)

☐ Form PTO-1449

☐ Citations

☐ Declaration of Biological Deposit

☐ Submission of "Sequence Listing," computer readable copy and/or amendment pertaining thereto for biotechnology invention containing nucleotide and/or amino acid sequence.

☐ Authorization of Attorney(s) to Accept and Follow Instructions from Representative

☐ Special Comments

☐ Other

5. Declaration or oath

☒ Enclosed

Executed by Jacquelyn R. Doyle and Kenneth F. Short

(check **all** *applicable boxes)*

☒ inventor(s).

☐ legal representative of inventor(s). 37 CFR 1.42 or 1.43.

☐ joint inventor or person showing a proprietary interest on behalf of inventor who refused to sign or cannot be reached.

☐ This is the petition required by 37 CFR 1.47 and the statement required by 37 CFR 1.47 is also attached. See item 13 below for fee.

☐ Not Enclosed.

WARNING: *Where the filing is a completion in the U.S. of an International Application, but where a declaration is not available, or where the completion of the U.S. application contains subject matter in addition to the International Application, the application may be treated as a continuation or continuation-in-part, as the case may be, utilizing ADDED PAGE FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION CLAIMED.*

☐ Application is made by a person authorized under 37 CFR 1.41(c) on behalf of *all the above named inventor(s)*.

(The declaration or oath, along with the surcharge required by 37 CFR 1.16(e) can be filed subsequently).

NOTE: It is important that all the correct inventor(s) are named for filing under 37 CFR 1.41(c) and 1.53(b).

☐ Showing that the filing is authorized.
(not required unless called into question. 37 CFR 1.41(d))

6. Inventorship Statement

WARNING: *If the named inventors are each not the inventors of all the claims an explanation, including the ownership of the various claims at the time the last claimed invention was made, should be submitted.*

The inventorship for all the claims in this application are:

☒ XX The same.

or

☐ Not the same. An explanation, including the ownership of the various claims at the time the last claimed invention was made,

☐ is submitted.

☐ will be submitted.

7. Language

NOTE: An application including a signed oath or declaration may be filed in a language other than English. A verified English translation of the non-English language application and the processing fee of $130.00 required by 37 CFR 1.17(k) is required to be filed with the application, or within such time as may be set by the Office. 37 CFR 1.52(d).

NOTE: A non-English oath or declaration in the form provided or approved by the PTO need not be translated. 37 CFR 1.69(b).

☒ English

☐ Non-English

☐ The attached translation is a verified translation. 37 CFR 1.52(d).

8. Assignment

☐ An assignment of the invention to None

☐ is attached. A separate ☐ "COVER SHEET FOR ASSIGNMENT (DOCUMENT) ACCOMPANYING NEW PATENT APPLICATION" or ☐ FORM PTO 1595 is also attached.

☐ will follow.

NOTE: "If an assignment is submitted with a new application, send two separate letters–one for the application and one for the assignment." Notice of May 4, 1990 (1114 O.G. 77-78).

WARNING: *A newly executed "CERTIFICATE UNDER 37 CFR 3.73(b)" must be filed when a continuation-in-part application is filed by an assignee. Notice of April 30, 1993, 1150 O.G. 62-64.*

9. Certified Copy N/A

Certified copy(ies) of application(s)

country	appln. no.	filed
country	appln. no.	filed
country	appln. no.	filed

from which priority is claimed

☐ is (are) attached.

☐ will follow.

NOTE: The foreign application forming the basis for the claim for priority must be referred to in the oath or declaration. 37 CFR 1.55(a) and 1.63.

NOTE: This item is for any foreign priority for which the application being filed directly relates. If any parent U.S. application or International Application from which this application claims benefit under 35 U.S.C. 120 is itself entitled to priority from a prior foreign application, then complete Item 18 on the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

10. Fee Calculation (37 CFR 1.16)

A. ☐ Regular application

CLAIMS AS FILED

Number filed	Number Extra		Rate	Basic Fee 37 CFR 1.16(a) $760.00
Total Claims (37 CFR 1.16(c))	8 − 20 = 0	×	$ 22.00	
Independent Claims (37 CFR 1.16(b))	1 − 3 = 0	×	$ 78.00	
Multiple dependent claim(s), if any (37 CFR 1.16(d))		+	$250.00	

☐ Amendment cancelling extra claims enclosed.

☐ Amendment deleting multiple dependencies enclosed.

☐ Fee for extra claims is not being paid at this time.

NOTE: If the fees for extra claims are not paid on filing they must be paid or the claims cancelled by amendment, prior to the expiration of the time period set for response by the Patent and Trademark Office in any notice of fee deficiency. 37 CFR 1.16(d).

Filing Fee Calculation $ 760.00

B. ☐ Design application
($310.00—37 CFR 1.16(f))

Filing Fee Calculation $_____

C. ☐ Plant application
($510.00—37 CFR 1.16(g))

Filing fee calculation $_____

11. Small Entity Statement(s)

☒ Verified Statement(s) that this is a filing by a small entity under 37 CFR 1.9 and 1.27 is (are) attached.

WARNING: *"Status as a small entity in one application or patent does not affect any other application or patent, including applications or patents which are directly or indirectly dependent upon the application or patent in which the status has been established. A nonprovisional application claiming benefit under 35 U.S.C. 119(e), 120, 121 or 365(c) of a prior application may rely on a verified statement filed in the prior application if the nonprovisional application includes a reference to a verified statement in the prior application or includes a copy of the verified statement filed in the prior application if status as a small entity is still proper and desired." 37 C.F.R. § 1.28(a).*

(complete the following, if applicable)

☐ Status as a small entity was claimed in prior application

_____ / _____, filed on _____, from which benefit is being claimed for this application under:

35 U.S.C. ☐ 119(e),
☐ 120,
☐ 121,
☐ 365(c),

and which status as a small entity is still proper and desired.

☐ A copy of the verified statement in the prior application is included.

Filing Fee Calculation (50% of **A, B** or **C** above) $ 380.00

NOTE: Any excess of the full fee paid will be refunded if a verified statement and a refund request are filed within 2 months of the date of timely payment of a full fee. The two-month period is not extendable under § 1.136. 37 CFR 1.28(a).

12. Request for International-Type Search (37 CFR 1.104(d))

(complete, if applicable)

☐ Please prepare an international-type search report for this application at the time when national examination on the merits takes place.

13. Fee Payment Being Made at This Time

☐ Not Enclosed

☐ No filing fee is to be paid at this time.
(This and the surcharge required by 37 CFR 1.16(e) can be paid subsequently.)

☒ Enclosed

☒ Basic filing fee $ 380.00

☐ Recording assignment ($40.00; 37 CFR 1.21(h)) (See attached "COVER SHEET FOR ASSIGNMENT ACCOMPANYING NEW APPLICATION".) $ _____

☐ Petition fee for filing by other than all the inventors or person on behalf of the inventor where inventor refused to sign or cannot be reached. ($130.00; 37 CFR 1.47 and 1.17(h)) $ _____

☐ For processing an application with a specification in a non-English language. ($130.00; 37 CFR 1.52(d) and 1.17(k)) $ _____

☐ Processing and retention fee ($130.00; 37 CFR 1.53(d) and 1.21(l)) $ _____

☐ Fee for international-type search report ($40.00; 37 CFR 1.21(e)) $ _____

NOTE: 37 CFR 1.21(l) establishes a fee for processing and retaining any application that is abandoned for failing to complete the application pursuant to 37 CFR 1.53(d) and this, as well as the changes to 37 CFR 1.53 and 1.78, indicate that in order to obtain the benefit of a prior U.S. application, either the basic filing fee must be paid, or the processing and retention fee of § 1.21(l) must be paid, within 1 year from notification under § 53(d).

Total fees enclosed $ 380.00

14. Method of Payment of Fees

☒ Check in the amount of $ 380.00

☐ Charge Account No. _____ in the amount of $_____
A duplicate of this transmittal is attached.

NOTE: Fees should be itemized in such a manner that it is clear for which purpose the fees are paid. 37 CFR 1.22(b).

15. Authorization to Charge Additional Fees

WARNING: If no fees are to be paid on filing, the following items should not be completed.

WARNING: Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges. If extra claim charges are authorized.

☐ The Commissioner is hereby authorized to charge the following additional fees by this paper and during the entire pendency of this application to Account No. _____:

☐ 37 CFR 1.16(a), (f) or (g) (filing fees)

☐ 37 CFR 1.16(b), (c) and (d) (presentation of extra claims)

NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 CFR 1.16(d)), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.

☐ 37 CFR 1.16(e) (surcharge for filing the basic filing fee and/or declaration on a date later than the filing date of the application)

☐ 37 CFR 1.17 (application processing fees)

WARNING: While 37 CFR 1.17(a), (b), (c) and (d) deal with extensions of time under § 1.136(a), this authorization should be made only with the knowledge that: "Submission of the appropriate extension fee under 37 C.F.R. 1.136(a) is to no avail unless a request or petition for extension is filed." (Emphasis added). Notice of November 5, 1985 (1060 O.G. 27).

☐ 37 CFR 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 CFR 1.311(b))

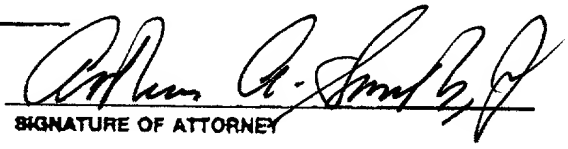
NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 CFR 1.311(b).

NOTE: 37 CFR 1.28(b) requires "Notification of any change in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying, . . . issue fee." From the wording of 37 CFR 1.28(b): (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

16. Instructions as to Overpayment

☐ Credit Account No. _____

☐ Refund



SIGNATURE OF ATTORNEY

Reg. No. 24,178

Arthur A. Smith, Jr.

(type or print name of attorney)

Tel. No. (617) 720-2750

149 North Street

P.O. Address

Boston, MA 02109

☐ **Incorporation by reference of added pages**

(check the following item if the application in this transmittal claims the benefit of prior U.S. application(s) (including an international application entering the U.S. stage as a continuation, divisional or C-I-P application) and complete and attach the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED)

☐ Plus Added Pages for New Application Transmittal Where Benefit of Prior U.S. Application(s) Claimed

Number of pages added_____

☐ Plus Added Pages for Papers Referred to in Item 4 Above

Number of pages added_____

☐ Plus "Assignment Cover Letter Accompanying New Application"

Number of pages added_____

☐ **Statement Where No Further Pages Added**

(if no further pages form a part of this Transmittal, then end this Transmittal with this page and check the following item.)

☒ This transmittal ends with this page.

Attorney's Docket No. KJ-100 **PATENT**

Applicant or Patentee: Jacquelyn R.Doyle and Kenneth F. Short

Application or Patent No. /

Filed or 371(c) date July 30, 1999

For: Wound Irrigation and Debriding System

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) and 1.27(b))—INDEPENDENT INVENTOR

As a below named inventor, I hereby declare that I qualify as an independent inventor, as defined in 37 CFR 1.9(c), for purposes of paying reduced fees under Sections 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office, with regard to the invention entitled Wound Irrigation and Debriding System described in

☒ the specification filed herewith.

☐ application no. /_____, filed _____.

☐ patent no. _____, issued _____.

I have not assigned, granted, conveyed or licensed, and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c), if that person had made the invention, or to any concern that would not qualify as a small business concern under 37 CFR 1.9(d), or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

☒ no such person, concern, or organization.

☐ persons, concerns or organizations listed below*

*NOTE: *Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)*

FULL NAME _____

ADDRESS _____

☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

FULL NAME _____

ADDRESS _____

☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

FULL NAME _____

ADDRESS _____

☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Jacquelyn R. Doyle
Name of inventor

Jacquelyn R. Doyle
Signature of Inventor — Date 7/22/99

Kenneth F. Short
Name of Inventor

Kenneth F. Short
Signature of Inventor — Date 7/22/99

Name of inventor

Signature of Inventor — Date

WOUND IRRIGATION AND DEBRIDING SYSTEM

FIELD OF THE INVENTION

This invention relates to medical apparatus for the irrigation and debriding of wounds and incisions and more particularly to a device in which a unit dose of sterile (USP) saline solution or a sterile water solution is dispensed for the irrigation and cleansing of a wound or incision.

BACKGROUND OF THE INVENTION

The accepted, long standing, current method of wound irrigation delivery systems is comprised of the following independently packaged items: a sealed sterilized bottle of saline solution, a sterile (e.g. 16oz.) bowl, and a sterile syringe. The accepted procedure involves opening all items, placing them onto a sterile field, unsealing the bottle of saline solution, pouring it into the now-opened bowl and then draw it up into the syringe. The system is now ready to irrigate the wound or incision. The two major drawbacks to the current system are as follows. The first drawback is the precious time that is lost, especially in an emergency, to unpack and assemble this system for use. The second, and most critical drawback, is the immediate exposure of all of these items to local contaminates. Once the seal on the bottle of saline solution is broken, the solution is now subject to contamination. This is even more so when the solution is poured into the now-exposed bowl. The already exposed solution is then drawn into the sterile syringe. The entire wound irrigation system is thus potentially contaminated. The sterile field on which this operation is performed is a sterilized, prepackaged sheet of paper that is removed from its protective packaging, unfolded and placed upon whatever surface the attending person is using for the procedure. If this surface becomes wet, it is then considered contaminated and rendered ineffective. The surface could be in a hospital operating or emergency room, a school nurse's office, an accident site, or a military field hospital. All are areas that could easily contaminate the exposed, current wound irrigation systems. An example of this contamination could be Staff Infection, which is easily spread, especially in hospital environments.

Although the current medical procedure has been in continuous use for quite some time, it would nevertheless, be extremely useful, if a suitable wound irrigation/debriding device could be provided which would avoid possible contamination of the irrigation solution.

It is, therefore, an object of the present invention to provide a quick, efficient and totally safe wound irrigation and debriding delivery system.

Another object of this invention is to provide a one-piece system, which can be pre-sterilized and easily stored in a ready-to-use condition to provide quick, safe and effective treatment when needed.

It is yet another object of this invention to provide a quick, easy-to-use, self-contained device which saves substantial time and expense.

It is yet another object of this invention to eliminate the Sharps Biohazard Waste associated with the prior art wound irrigation systems. These current systems employ the use of a needless syringe. This syringe must be discarded into a Sharps Hazard Container, at considerable cost to the facility. The present invention eliminates all Sharps Hazards in the wound irrigation process.

SUMMARY OF THE INVENTION

An improved medical procedure and apparatus has been discovered for the irrigation of wounds and incisions which is not prone to the contamination dangers of prior-art systems. The invention consists of the irrigation solution, an irrigation solution chamber, a nozzle, a nozzle protective tip with a removable packaging band around it for additional protection during storage and moving and an optional filter. In one embodiment, the nozzle assembly is screwed onto the solution chamber at point of manufacture,, In another embodiment, the nozzle and solution chamber are molded into one unit during the manufacturing process. The entire device is made of a flexible material, preferably plastic. All separate items, of each embodiment, are assembled into one unit, sterilized, and packaged at the point of manufacture and shipped ready to use. Preferred quantities and type of irrigation solution are 120-200 cc of USP saline solution or of distilled water.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other objects of the present invention and the various features and details of the operation and construction thereof are hereinafter more fully set forth with reference to the accompanying drawings, where:

Fig. 1 is a perspective view of the complete assembly with a nozzle.

Fig. 2 is a perspective view of the solution chamber used with a screw-on nozzle.

Fig. 3 is a perspective view of a straight screw-on nozzle.

Fig. 4 is a perspective view of an angled screw-on nozzle.

Fig. 5 is a perspective view of an optional filter.

Fig. 6 is a perspective view of a molded assembly.

DETAILED DESCRIPTION OF THE INVENTION

The preferred embodiment of the invention, as shown in Fig. 1, comprises solution chamber 10 containing sterile irrigation solution 11; chamber 10 being affixed to and opening into delivery nozzle 14, which contains optional filter 15; the delivery end of said nozzle 14 having protective tip 13 around which is wrapped packaging band 12. Nozzle 14 may be configured (Fig. 3) to screw onto solution chamber 10 (Fig. 2) or it may be molded as one piece to the solution chamber (Fig. 6). Both configurations are assembled at point of manufacture into a single-piece, disposable, sterile unit.

Although the nozzles shown in Figs. 1 and 3 are straight, they may also be fabricated with varying degrees of angles as shown, for example, in Fig. 4. A typical (optional) filter 15 for the unit is shown in Fig. 5.

When it is necessary to use the assembly, it is taken from its place of storage into the general area of use as, for example, a hospital emergency room, outpatient clinic, operating room, nursing station, patient room, physician's office, field hospital, or other medical/veterinarian application.

The device of the present invention is free standing and can be conveniently placed anywhere in the sterile field being used for this procedure. When ready for use, packaging band 12 is removed. The protective tip 13 is then removed from the nozzle and the irrigation process is effected by applying hand pressure to the walls of solution chamber 10. The sterile irrigation solution (a distilled water or a USP saline solution) passes from the chamber 10, through nozzle 14 to the wound area. When solution flow is stopped, the air reentering chamber 10 may be further protected from contamination by employing optional filter 15. Filter 15 is located between the end of nozzle 14 at the inlet into solution chamber 10. Filter 15 is a diaphragm-type valve. For example, one embodiment is a Mitral filter valve, which is a diaphragm of filter medium that expands under internal pressure to create an orifice and collapses back into place with the release of internal pressure. Another embodiment is a Clapper Filter, which is filter medium assembled to a one-directional clapper valve frame. Both filter types operate on the same basis. When pressure is applied from inside, filter 15 opens to allow passage of fluid from chamber 10 through delivery nozzle 14 and tip 13 to the wound. When inside pressure is released the returning air to chamber 10 returns filter 15 to its original position, thereby allowing the filtration of the returning air to chamber 10. This filtration minimizes the contamination of the remaining irrigation solution during necessary interruptions in the irrigation treatment. Since the entire assembly can be placed in an upright, free standing, position, nozzle 14 is prevented from possible contact with contaminated areas, allowing for safer interruptions of the wound care procedure. When irrigation solution 11 is depleted, the empty device may be discarded in its entirety, in any common waste receptacle. No Sharps Hazard Disposal requirements apply to the device of the present invention.

What is claimed is:

1. A sterile, disposable dispenser for the irrigation and debriding of wounds and incisions, comprising:

a flexible chamber having an internal volume containing a sterile solution, said chamber having an orifice at one end thereof;

a nozzle having a first opening at one end and a second opening at the other end thereof, wherein said first opening is affixed to said orifice of said chamber; and said second opening dispenses said solution;

a protective tip affixed to said second opening of said nozzle, thereby maintaining said solution in a sterile state; and

a removable packaging band around said protective tip.

2. The dispenser of claim 1 wherein said nozzle contains a filter at said first opening.

3. The dispenser of claim 1 wherein said nozzle has a screw-on cap affixing said first opening to said orifice of said chamber.

4. The dispenser of claim 1 wherein said nozzle is molded to said chamber.

5. The dispenser of claim 1 wherein said nozzle is angled.

6. The dispenser of claim 1 wherein said nozzle is straight.

7. The dispenser of claim 1 wherein said sterile solution contains 0.9 percent USP sodium chloride.

8. The dispenser of claim 1 wherein the said sterile solution contains 0.9 percent distilled water.

ABSTRACT

A device for use as a pre-filled, self contained, single use, disposable, sterile wound irrigation and debriding system, comprising a pre-filled unit of USP saline solution or distilled water, preferably 120-200 cc. The unit is a flexible, free standing, chamber containing the saline solution and affixed to a nozzle, which may be straight or angled, having a delivery tip and optional return air filter. The device of the present invention is provided in two embodiments, the first being one in which the nozzle is screwed onto the chamber, and the second being a single molded unit. In both configurations, the device is pre-filled, fully assembled, sterilized and packaged at point of manufacturing and delivered in a no- assembly required, ready to use state. The material need for the device is flexible, preferably plastic.

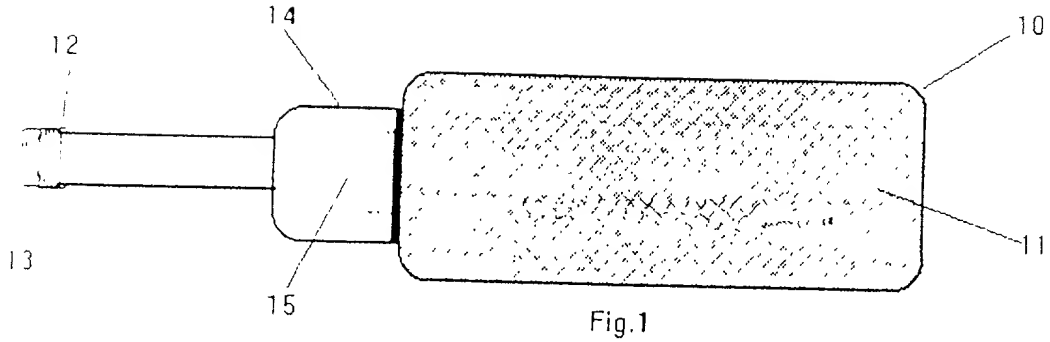


Fig.1

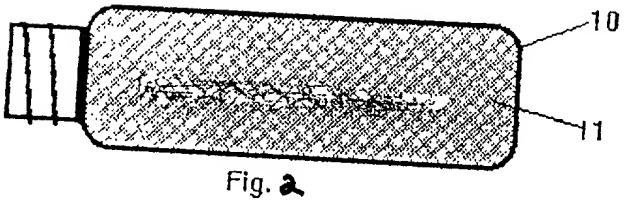


Fig. 2

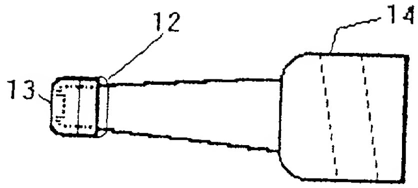


Fig. 3

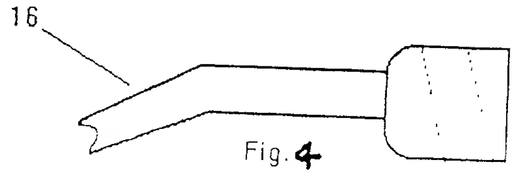


Fig. 4

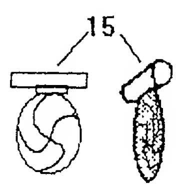


Fig. 5

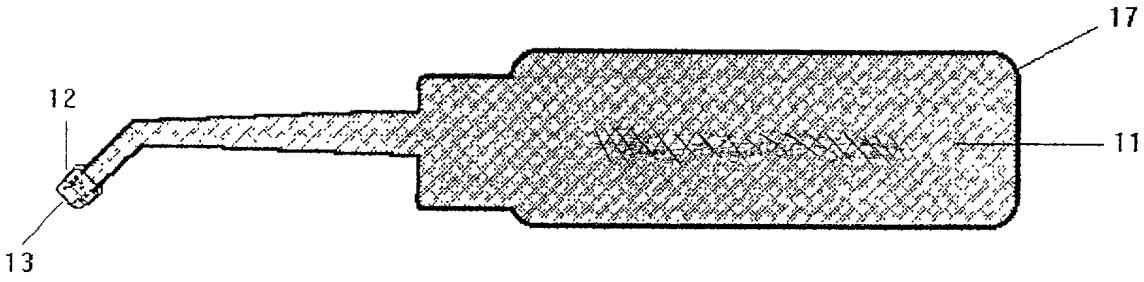


Fig. 6

ATTORNEY'S DOCKET NUMBER

KJ-100

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am ~~the original, first and sole inventor (if only one name is listed below) or~~ an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

Wound Irrigation and Debriding System

the specification of which
(check one) XX is attached hereto.
___ was filed on _____ as
Application Serial No. _____
and was amended on _____.
(if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, § 1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s) NONE

			Priority Claimed	
(NUMBER)	(COUNTRY)	(DAY/MONTH/YEAR FILED)	YES	NO
(NUMBER)	(COUNTRY)	(DAY/MONTH/YEAR FILED)	YES	NO
(NUMBER)	(COUNTRY)	(DAY/MONTH/YEAR FILED)	YES	NO

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application: NONE

(APPLICATION SERIAL NO.)	(FILING DATE)	(STATUS) (PATENTED, PENDING, ABANDONED)
(APPLICATION SERIAL NO.)	(FILING DATE)	(STATUS) (PATENTED, PENDING, ABANDONED)

I HEREBY APPOINT THE FOLLOWING AS MY ATTORNEY OR AGENT(S) WITH FULL POWER OF SUBSTITUTION TO PROSECUTE THIS APPLICATION AND TRANSACT ALL BUSINESS IN THE PATENT OFFICE CONNECTED THEREWITH:

Name	Reg. No.	Name	Reg. No.	Name	Reg. No.
Arthur A. Smith, Jr.	24,178				

SEND CORRESPONDENCE TO:

NAME	PHONE NO.	STREET	CITY & STATE	ZIP CODE
Arthur A. Smith, Jr.	(617)720-2750	149 North Street	Boston MA	02109

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first ~~inventor~~ Jacquelyn R Doyle

Inventor's signature Jacquelyn R Doyle Date 7-22-99

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Second Inventor's signature Kenneth F Short Date 7/22/99

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Inventor's signature Date

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Full name of fourth joint inventor, if any

Inventor's signature Date

Residence

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Post Office Address

Full name of fifth joint inventor, if any

Inventor's signature Date

Residence

Citizenship

Post Office Address